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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/828,838	04/20/2004	Stephanie M. Kladakis	022956-0261	5281

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EXAMINER

WOODWARD, CHERIE MICHELLE

ART UNIT	PAPER NUMBER
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1647

NOTIFICATION DATE	DELIVERY MODE
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10/16/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docket@nutter.com

Office Action Summary	Application No. 10/828,838	Applicant(s) KLADAKIS ET AL.	
	Examiner CHERIE M. WOODWARD	Art Unit 1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 June 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8, 10-14, 16-21, 23-27 and 29-33 is/are pending in the application.
- 4a) Of the above claim(s) 29-31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 10-14, 16-21, 23-27 and 29-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>1/24/2008</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/30/2008 has been entered.

Formal Matters

2. Claims 1-8, 10-14, 16-27, and 29-33 are pending. Claims 9, 15, 22, 28, and 34 have been cancelled by Applicant. Claims 29-31 remain withdrawn as being drawn to non-elected inventions. Claims 1-8, 10-14, 16-21, 23-27, and 32-33 are under examination.

Response to Arguments

Claim Objections/Rejections Withdrawn

1. The rejection of claims 1-8, 10-14, 16-27, and 32-34 under 35 U.S.C. 112, second paragraph, as being indefinite regarding the phrase "high density," is withdrawn in light of Applicant's amendments.
2. The rejections of claims 22 and 34 are withdrawn as moot in light of Applicant's cancellation of the claims.

Claim Rejections Maintained

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claims 1-8, 10-14, 16-21, 23-27, and 32-33 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Bowman et al. U.S. Patent Publication US 20020127265 (12 September 2002) and Huckle et al., WO 01/85226 (published 15 November 2001), as exemplified by Boland et al., (J Macromol Sci –Pure Appl Chem. 2001;A38(12):1231-1243), for the reasons of record and the reasons set forth herein.

Applicant argues the amendments obviate the obviousness rejection, based on the examiner's remarks to the Advisory Action mailed 24 June 2008, stating that further search and consideration would be required (Remarks, p. 7, first paragraph). Applicant reiterates the arguments presented in the Supplemental Response filed 15 May 2008 (Remarks, p. 7, first paragraph). Applicant argues that the examiner has not made out a *prima facie* case of equivalence regarding the teachings in Bowman (Remarks, p. 7, second paragraph). Applicant argues that the examiner has failed to provide an explanation and rationale as to why the density of Bowman's mesh would be equivalent to the claimed nonwoven polymeric material density (Remarks, p. 7, second paragraph). Applicant argues that "the mere fact that the density of Bowman's mesh 'is a testable physical property' does not support the contention that Bowman's mesh is equivalent to the claimed nonwoven polymeric material or that Bowman's mesh would be equivalent to the claimed nonwoven polymeric material" (Remarks, p. 7, second paragraph). Applicant argues that the instant specification and the teachings of Bowman tend to show nonequivalence (Remarks, p. 8, first paragraph). Applicant also argues that Bowman fails to teach or suggest that the mesh material has a density in the claimed range (Remarks, p. 8, first paragraph).

Applicant argues that the examiner is incorrect about Bowman setting forth any strain requirements (Remarks, p. 8, third paragraph), although Applicant acknowledges that the examiner specifically stated that "Bowman does not explicitly teach the specific modulus of elasticity...of the claimed scaffold" (Remarks, p. 8, second paragraph). Applicant argues that the modulus of elasticity is the ratio of stress to strain (Remarks, p. 8, last paragraph). Applicant argues that none of the values provided by Bowman in paragraph 30 are a strain that can be used to calculate the modulus of elasticity

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(Remarks, p. 8, last paragraph). Applicant argues that paragraph 31 of Bowman suggests that the modulus of elasticity of the elastomers disclosed by Bowman would be lower than the claimed range (Remarks, p. 9, first paragraph).

Applicant's arguments have been fully considered, but they are not persuasive. Regarding Applicant's assumptions about After-Final practice and the examiner's statements regarding the need for additional search and consideration, Applicant is directed to MPEP 714.12 and 37 CFR 1.116. MPEP 714.12 states that once a final rejection that is not premature has been entered in an application, an applicant or patent owner no longer has any right to unrestricted further prosecution. The examiner stated in the Advisory Actions of record that Applicant's amendments to the claims required further search and consideration because of the specific limitations of the claim amendments. Applicant is incorrect to assume that the examiner's statement meant that the rejection under 35 USC 103(a) had been obviated or overcome. A further search and consideration has revealed that the added limitations are indeed taught by the prior art. Density limitations within the claimed range of 120 mg/cc (taught in units of mg/cm^3) are taught by the '226 publication at page 21, line 34.

In response to Applicant's reiteration of the arguments presented in the Supplemental Response filed 15 May 2008 (Remarks, p. 7, first paragraph), the examiner reiterates her reply to those arguments, as set forth in the Advisory Action of 6/24/2008.

Regarding Applicant's argument as to the density and "equivalency" of the scaffold taught in the prior art, Applicant's argument misunderstands the examiner's statements. The issue is not one of equivalency. The subject of equivalency was previously raised by the examiner, but only in regard to the "dry-laid" material (see specification p. 7, paragraphs 46 and 47, and the Office Action mailed 12/31/2007, page 5, last paragraph to page 6, first paragraph). The concern of the examiner regarding the modulus of elasticity is directed to inherent intrinsic physical properties of the composition. The absence of explicit strain measurements in the '265 publication does not obviate the examiner's argument, where the physical property in question is testable. The examiner previously directed Applicant to paragraph 31 of the '265 publication which recites "[i]n addition to these elongation and modulus properties, suitable elastomers should also have a tensile strength greater than about 500 psi, preferably greater than about 1,000 psi, and a tear strength of greater than about 50 lbs/inch, preferably greater than about 80 lbs/inch." Because the modulus of elasticity is the ratio of stress to strain, the '265 publication provides sufficient evidence to suggest that, absent evidence to the contrary, the scaffolds taught therein would likely have a modulus of elasticity greater than about 1.5MPa, based on the stress and strain requirements set forth in the '265 publication. The examiner has provided evidence in the art that the modulus of elasticity (the

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ratio of stress to strain) is a testable physical property of a composition. The examiner has stated that the USPTO does not have the facilities available to run a modulus of elasticity test on the scaffold of the prior art and the instantly claimed scaffold and compare and contrast the differences. The examiner has stated that the burden is on Applicant to provide data or evidence that the modulus of elasticity of the prior art scaffold would not meet the limitations of the instant claims. See *In re Brown*, 59 CCPA 1036, 459 F.2d. 531, 173 USPQ 685 (CCPA 1972) (holding at 1041, “[a]s a practical matter, the Patent Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make physical comparisons therewith”) and *Ex parte Gray*, 10 USPQ 2d 1922, 1924-25 (PTO Bd. Pat. App. & Int.). Instead of Applicant providing data or evidence, the examiner has only been presented with attorney argument and elementary-level definitions of modulus of elasticity. Additionally, Applicant has provided no evidence to support the hypothesis that paragraph 31 of Bowman suggests that the modulus of elasticity of the elastomers disclosed by Bowman would be lower than the claimed range (Remarks, p. 9, first paragraph). As previously stated of record, Applicant is in the best position to provide the required data and evidence and the case law clearly states that the burden is on the Applicant to provide the required data/evidence.

As previously stated of record, it would have been *prima facie* obvious to the person of ordinary skill in the art at the time the invention was made to combine the teachings of Bowman et al., and Huckle et al., to produce a biocompatible scaffold comprising a nonwoven polymeric material from dry laid polymer to provide increased suture-pull out strength. Additionally, Huckle et al., teach that random entanglement in the nonwoven scaffold provides a large surface area for cell attachment or capture during cellular in-growth. One of skill in the art reasonably would have expected success because Huckle et al., teach dry-laid nonwoven scaffolds used in that provide superior strength for the implant. The methods of producing the nonwoven components, whether by a wet lay process (i.e. electrospinning) or by a dry laid process, are taught as equivalents by Huckle et al., and thus, one would reasonably expect to produce a strong scaffold using either or both processes.

Provisional Obviousness-Type Double Patenting Rejection

6. Claims 1-8, 10-14, 16-27, and 32-33 remain provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-14, 17-29, and 32 of copending Application No. 11/427,477, for the reasons of record and the reasons set forth herein. The instant claims are not in condition for allowance and as such, the rejection is maintained.

New Claim Rejections
Provisional Obviousness-Type Double Patenting Rejections

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 1, 7, 10-14, 19, and 24-27 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 8-11 of copending Application No. 11/856,743. The conflicting claims of the instant application and the '743 application are drawn to tissue repair/growth devices comprising a biocompatible and biodegradable scaffold permitting cell in-growth. The instant claims differ in scope from the claims of the '743 application in that the instant claims represent a species of the genus claimed in the '743 application. A species anticipates the genus. Additionally, compare paragraph 36 and Figure 5 of the '743 application with instant Figures 1A, 1B, 2A, 2B and paragraph 51 (p. 8 of the specification). Applicant is reminded that MPEP § 804 (II) states, “When considering whether the invention defined in a claim of an application would have been an obvious variation of the invention defined in the claim of a patent, the disclosure of the patent may not be

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used as prior art. *General Foods Corp. v. Studiengesellschaft Kohle mbH*, 972 F.2d 1272, 1279, 23 USPQ2d 1839, 1846 (Fed. Cir. 1992). This does not mean that one is precluded from all use of the patent disclosure.” (Emphasis added). “Further, those portions of the specification which provide support for the patent claims may also be examined and considered when addressing the issue of whether a claim in the application defines an obvious variation of an invention claimed in the patent. *In re Vogel*, 422 F.2d 438, 441-42, 164 USPQ 619, 622 (CCPA 1970).”

9. Claims 1, 7, 8, 19, 24-27, 32, and 33 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 5, 7-9, 12, and 13 of copending Application No. 11/856,741. The conflicting claims of the instant application and the '741 application are drawn to tissue repair devices comprising a biocompatible and biodegradable scaffold permitting cell in-growth. The instant claims differ in scope from the claims of the '741 application in that the instant claims represent a species of the genus claimed in the '741 application. A species anticipates the genus. Also compare the instant specification at paragraphs 66 and 67 (p. 12-13) regarding allogenic and autogenic tissue and the inclusion of fibrin. Applicant is reminded that MPEP § 804 (II) states, “When considering whether the invention defined in a claim of an application would have been an obvious variation of the invention defined in the claim of a patent, the disclosure of the patent may not be used as prior art. *General Foods Corp. v. Studiengesellschaft Kohle mbH*, 972 F.2d 1272, 1279, 23 USPQ2d 1839, 1846 (Fed. Cir. 1992). This does not mean that one is precluded from all use of the patent disclosure.” (Emphasis added). “Further, those portions of the specification which provide support for the patent claims may also be examined and considered when addressing the issue of whether a claim in the application defines an obvious variation of an invention claimed in the patent. *In re Vogel*, 422 F.2d 438, 441-42, 164 USPQ 619, 622 (CCPA 1970).”

Conclusion

NO CLAIM IS ALLOWED.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHERIE M. WOODWARD whose telephone number is (571)272-3329. The examiner can normally be reached on Monday - Friday 9:00am-5:30pm (EST).

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath N. Rao can be reached on (571) 272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Cherie M. Woodward/
Examiner, Art Unit 1647